JUL 1 - 2005

K051184

United Contact Lens
SOFT CONTACT LENSES

19111 – 61st Avenue NE, Suite 5. Arlington, Washington 98223
Office: 425-743-7343 Fax: 425-743-8795 Toll Free: 800-446-1666

510(k) Summary

Submitter Information:

United Contact Lens Inc.
19111 61st Ave. NE #5
Arlington, WA 98223
Registration No. 2918644

Contact Person: Garold L. Edwards, O.D., F.A.A.O.
Regulatory Consultant
Telephone: (408) 221 - 3860
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Date Prepared: May 4, 2005

Device Name:

Common Name: Soft (Hydrophilic) Contact Lens

Trade/Proprietary Names: 55 SV (ocufilcon C) Soft (Hydrophilic) Contact Lens for Daily Wear

55 Multifocal (ocufilcon C) Soft (Hydrophilic) Contact Lens for Daily Wear

55 Toric (ocufilcon C) Soft (Hydrophilic) Contact Lens for Daily Wear

Classification Name: Soft (Hydrophilic) Contact Lens

Device Classification: Class II (21 CFR 886.5925)

Predicate Devices:

The 55 F (ocufilcon C) Soft (Hydrophilic) Single Vision Contact Lens, the 55 Multifocal (ocufilcon C) Soft (Hydrophilic) Contact Lens and the 55 Toric Contact Lens were selected as the predicate devices manufactured in the same facility, using the same formulation, under the same quality system packaging and sterilization processes as the subject devices.

Description of Devices:

The 55 SV, 55 Multifocal, and the 55 Toric (ocufilcon C) Soft (Hydrophilic) Daily Wear Contact Lenses are hemispherical flexible shells which cover the cornea and a portion of the adjacent sclera. The 55 Contact Lens is available in a single vision lens design, the 55 Toric Contact Lens is available in a double slab-off back surface design and the 55 Multifocal Contact Lens is available in an aspheric lens design. The lens material (ocufilcon C) is a hydrophilic polymer of 2-hydroxyethyl methacrylate (HEMA) and methacrylic acid cross-linked with ethyleneglycol dimethacrylate (45.0%) and water (55.0%). Lenses are tinted using the color additive Reactive Blue 19.

Comparison to Predicate Device

PARAMETER ***Submission number***	***55 SV, 55 Toric and 55 Multifocal Soft (hydrophilic) Contact Lenses for Daily Wear N/A***	***55 F, Toric 55 and Multifocal (ocufilcon C) Soft (hydrophilic) Contact Lenses for Daily Wear P920008/K941607***
Material	ocufilcon C	ocufilcon C
Material classification	Hydrophilic Lens Group 4	Hydrophilic Lens Group 4
Indication for use	myopia, hyperopia, astigmatism and presbyopia	myopia, hyperopia, astigmatism and presbyopia
Water content	54.9%	54.4%
Visible light transmittance	98.9%	98.3%
Dk (35° C)	18.77×10^{-11}	18.78×10^{-11}
Powers	+12.00 D to -20.00 D; Continuous add power to +3.00 (55 Multifocal only); Cylinder powers -0.50 D to -2.50 D (55 Toric only)	+20.00D to –20.00 D Continuous add power to +3.00 (55 Multifocal only); Cylinder powers : -0.50 D to – 6.00D (Toric 55 only)
Color	Blue visibility, Reactive Blue #19	clear
Refractive index	*1.415*	1.414
Method of manufacture	Molded	Lathed

Indications for Use:

The **55 SV (ocufilcon C) Soft (Hydrophilic) Contact Lens** is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic or not-aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 diopters that does not interfere with visual acuity.

The **55 Multifocal (ocufilcon C) Soft (Hydrophilic) Contact Lens** is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic or not-aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 diopters that does not interfere with visual acuity.

The 55 Toric (ocufilcon C) Soft (Hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or not aphakic persons with non- diseased eyes.

The lenses may be disinfected using chemical or hydrogen peroxide disinfecting systems. Eye care practitioners may prescribe the lenses for daily wear and/or frequent replacement. When prescribed for a Frequent Replacement Program, the lenses may be disinfected using chemical or hydrogen peroxide disinfecting systems.

Description of Safety and Substantial Equivalence:

A series of pre-clinical tests were performed to demonstrate the safety and effectiveness of the 55 SV, the 55 Multifocal, and the 55 Toric (ocufilcon C) Soft (Hydrophilic) Contact Lenses for Daily Wear, and to establish substantial equivalence to the predicate devices.

Results of Systemic Injection, Primary Ocular Irritation and Cytotoxicity Tests show the lenses to be non-toxic and non-irritating. The 55 SV lenses were extracted and evaluated for presence of residue. Results showed no evidence of unsafe amounts of residue in the extracts. Physicochemical testing of the 55 lenses demonstrated equivalency to the predicate devices.

Conclusion:

Information submitted in the 510(k) establishes that the 55 SV, the 55 Multifocal and the 55 Toric Contact Lenses (ocufilcon C) have comparable physicochemical properties to the predicate devices and do not raise questions of safety and effectiveness. Shelf life testing has shown the lenses remain sterile and that the physical lens properties are stable. Therefore, the devices are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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United Contact Lens, Inc.
c/o Garold L. Edwards, O.D., F.A.A.O
Regulatory Consultant
2091 Upper Scenic Drive
Felton, CA 95018

Re: K051184
Trade/Device Name:
55 SV (ocufilcon C) Soft (hydrophilic) Contact Lens for Daily Wear
55 Multifocal (ocufilcon C) Soft (hydrophilic) Contact Lens for Daily Wear
55 Toric (ocufilcon C) Soft (hydrophilic) Contact Lens for Daily Wear
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL
Dated: May 4, 2005
Received: May 9, 2005

Dear Mr. Edwards:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS STATEMENT

Device Names:

55 SV (ocufilcon C) Soft (Hydrophilic) Contact Lens for Daily Wear

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Prescription Use X OR Over-the-Counter Use_____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald W. Chapman, Ph.D.

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K051184